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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,053	07/24/2003	Claus Yding Andersen	6203.214-US	1429
7590	08/11/2006		EXAMINER	
Reza Green Novo Nordisk Pharmaceuticals, Inc. 100 College Road West Princeton, NJ 08540				SAUCIER, SANDRA E
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,053	ANDERSEN ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 July 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 19,21 and 23-43 is/are pending in the application.
- 4a) Of the above claim(s) 25,26 and 30-41 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 19,21,23,24,27-29,42 and 43 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 24 July 2006 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09/929800.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claims 19, 21, 23–43 are pending. Claims 19, 21, 23, 24, 27–29, 42 and 43 are considered on the merits. Claims 25, 26, 30–41 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Applicants species election of FF-MAS for examination is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The disclosure is objected to because of the following informalities: The first paragraph of the specification should be updated as to the status of priority/continuity information in it. Appropriate correction is required.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections – 35 USC § 112

INDEFINITE

Claims 19, 21, 23, 24, 27–29, 42 and 43 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are replete with abbreviations. Please do not use abbreviations in the claims at least without prior definition in the claims. It is much preferred to use 4,4-dimethyl-5 α -cholesta-8,14,24-triene-3 β -ol instead

to the non-art accepted abbreviation, FF-MAS, which may lead to unfavorable interpretations of the claims.

Claims 19, 43 recite the use of “a MAS analogue”. However, this term is indefinite because the metes and bounds of the term and therefore, the claim cannot be understood. How much variation is allowed for a sterol to be termed an analogue. For example, cholesterol clearly has the same basic sterol structure as lanosterol and might be termed an analogue of lanosterol or of 4,4-dimethyl-5 α -cholesta-8,14,24-triene-3 β -ol.

Claim 19 uses MII which is not defined.

Claim 21 uses M11 which is not defined.

Claim 43 uses ‘Mil” which is not defined.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 21, 23, 24, 27–29, 42 and 43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5,716,777 [A] or WO 96/00235 [N] in light of Smitz *et al.* [U].

The claims are directed to a method for *in vitro* fertilization comprising: culturing oocytes in metaphase II with spermatozoa in a culture medium which comprises MAS, MAS analogue, additive capable of stimulation of the production of MAS, thereby forming zygotes or pre-embryos.

The elected species is FF-MAS which is 4,4-dimethyl-5 α -cholesta-8,14,24-triene-3 β -ol.

The references are relied upon as explained below.

US 5,716,777 or WO 96/00235 contain essentially the same material. The references disclose that "when *in vitro* fertilization is performed, better results are achieved, when a meiosis inducing substance of formula (I) is added to the medium in which the oocytes are kept." The compounds of formula (I), include 4,4-dimethyl-5 α -cholesta-8,14,24-triene-3 β -ol, col. 5.

Smitz *et al.* is a review which demonstrates what is known in the art of *in vitro* fertilization. It shows schematically in Figure 1, the different techniques to culture oocytes in relation to the stage of development of the oocyte. The culturing of oocyte-cumulus complex as well as of a denuded oocyte is demonstrated. After ovulation induction for IVF, 80% of the harvested oocytes are metaphase II and the remaining oocytes are either metaphase I or GV (page 150). Therefore incubation of these oocytes, as is routine in the art, would include metaphase I, metaphase II and GV oocytes and lead to even more of the oocytes becoming mature. Routinely, for *in vitro* fertilization, spermatozoa are added to the medium and oocytes allowed to be fertilized and divide, prior to selection of a few for implantation.

Thus, the teaching of US 6,716,777 of the addition of a meiosis-stimulating sterol to the incubation medium of the oocyte in a method of *in vitro* fertilization, inherently incorporates all the steps routine in *in vitro* fertilization methods.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19, 21, 23, 24, 27–29, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smitz *et al.* [U] or Barnes *et al.* [W] or US 5,693,534 [B] in combination with US 5,716,777 [A] or WO 96/00235 [N].

The claims have been discussed above.

US 5,716,777 and WO 96/00235 and Smitz *et al.* were explained above.

Barnes *et al.* is cited to show what is known in the art of IVF and ICSI (page 3244). Namely, that immature oocytes are cultured in medium and exposed to spermatozoa and allowed to form zygotes.

US 5,693,534 is cited to show what is known and routine in the art of IVF (cols. 5 and 6).

Smitz *et al.*, Barnes *et al.* and US 5,693,534 lack the inclusion of a sterol in the medium used for oocyte maturation and fertilization.

The addition of a meiosis stimulating sterol such as FF-MAS to the culture medium of oocytes used in IVF would have been obvious when taken with US 5,716,777 or WO 96/00235 because both suggest such an addition.

One of ordinary skill in the art would have been motivated at the time of invention to make this addition in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier

Primary Examiner
Art Unit 1651
August 8, 2006